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1. Purpose/Policy

The purpose of this document is to specify criteria that shall be used by recognized Auditing Organizations to determine the audit time necessary to conduct an audit of a medical device manufacturer for regulatory purposes according to the Medical Device Single Audit Program (MDSAP).

2. Scope

This document applies to MDSAP recognized Auditing Organizations conducting audits of a medical device manufacturer for regulatory purposes. Adherence to this document and its requirements will help mitigate the risk of inconsistent audit times being calculated by different Auditing Organizations performing similar audit activities within the medical device single audit program.

3. Definitions/Acronyms

Audit: A systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled. (ISO 9000:2015 clause 3.9.1)

Audit Time: Time needed to plan and accomplish a complete and effective audit of the client organization's management system (ISO/IEC 17021-1:2015 clause 3.6)

Auditing Organization (AO): An organization that audits a medical device manufacturer for

conformity with quality management system requirements. Auditing organizations may be an independent commercial organization or a Regulatory Authority which perform regulatory audits. (IMDRF/ MDSAP WG/N5)

Auditor: A person with the demonstrated personal attributes and competence to conduct an audit. (ISO 9000:2015 clause 3.9.9)

Auditor Day: Eight (8) hours excluding breaks, meals, and travel

Duration of Audit: Part of *audit time* spent conducting audit activities from the opening meeting to the closing meeting, inclusive (ISO/IEC 17021-1:2015 clause 3.17)

Regulatory Authority: A government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements. (GHTF/SG1/N78:2012)

4. Responsibilities

The Auditing Organization shall comply with this procedure as well as all applicable clauses of ISO/IEC 17021-1:2015 (e.g. clause 9.1.4) when calculating duration of audit and determining audit time.

It is the responsibility of the Auditing Organization to maintain documented evidence of the calculations (and other justifications) used to determine the audit time necessary to conduct audits of medical device manufacturers for regulatory purposes.

Note 1: It is recognized that Auditing Organizations may be subjected to further requirements of other ISO 13485 certification schemes. This may influence the calculated audit time.

Note 2: As this is a novel procedure for determining the audit time, the Auditing Organization is expected to collect and evaluate information from the MDSAP auditors regarding the calculated duration of audit versus the actual/needed duration of audit. Such data may be used by the participating Regulatory Authorities for a later review and revision of this procedure.

5. Procedures

5.1 *Off-site Audit Time Determination:*

Off-site audit time (e.g. preparation, report writing, etc.) is to be determined by auditing organization policies and procedures.

5.2 *Duration of Audit Calculation:*

The MDSAP audit model defines the MDSAP Audit Cycle including what constitutes Initial

Certification (Stage 1 and 2), Surveillance, Re-audits (a.k.a. Recertification Audits), and Special Audits.

The duration of audit for each "type" of audit will vary due to the scope and criteria established for each audit. The appropriate criteria defined within the MDSAP Audit Cycle must be used when calculating duration of audit. When applicable, the appropriateness of the duration of audit for subsequent activities should be confirmed during the Stage 1 audit.

The MDSAP audit model contains the purpose and anticipated outcomes when auditing seven (7) specific quality management system processes. The mechanism for auditing these quality management system processes and achieving the anticipated outcomes is the accomplishment of specific audit "tasks". There are varying numbers of audit tasks depending on the process being audited.

The number of audit tasks accomplished during the audit of a medical device manufacturer will vary depending on the type of audit performed and the specific activities performed by the organization.

For example: If the organization does not manufacture sterile medical devices (or medical devices subject to sterilization by the user) and the devices do not require installation, or servicing, Production and Service Controls tasks 9, 26, and 27 will not be applicable and should not be considered in duration of audit calculations. Conversely, if more than one design or more than one manufacturing process is selected for audit, the addition of duplicate audit tasks may need to be considered when making duration of audit calculations since the same tasks will be applied during multiple audit activities.

Duration of audit is calculated based on the number of applicable audit tasks associated with the type of audit to be conducted (as defined in the MDSAP Audit Cycle) and the specific activities of the organization to be audited.

The chart below summarizes the process for determining the duration of audit calculations. The time required to accomplish the individual audit tasks has been calculated based on empirical data generated from the validation of a similar "task-based" audit model where ever possible. *MDSAP AU F0008.1 and MDSAP AU F0008.2 cited (and embedded) below contain instructions and fillable Excel spreadsheet options for automatically calculating duration of audit based on the tasks and times cited below.*

MDSAP Process	MDSAP Tasks per Process	Number of Applicable Tasks to be Audited A	Minutes per Audit Task B	Total Number of Minutes per Process A × B	Audit Hours per Process A × B ÷ 60	MDSAP On-site Auditor Days A × B ÷ 60 ÷ 8
Management	11		**28.8**			
DMA&FR	3		**28.0**			
MA&I	16		**30.4**			
MDAE&ANR	2		**30.4**			

D&D	17		**16.8**			
P&SC	29		**35.2**			
Purchasing	16		**12.0**			
Total	94					

Management = Management Process
DMA&FR = Device Marketing Authorization and Facility Registration Process
MAI = Measurement, Analysis and Improvement Process
MDAE&ANR = Medical Device Adverse Events and Advisory Notices Reporting Process
D&D = Design and Development Process
P&SC = Process and Service Controls Process
Purchasing = Purchasing Process

*Calculating Duration of Audit – for audits **excluding** Stage 1:* Apply MDSAP duration of audit adjustments *(5.3)* as applicable. Use MDSAP P0008 algorithm contained within the chart above to calculate the total time necessary to accomplish all applicable audit tasks.

*Calculating Duration of Audit – for **initial** certification audits (Stage 1 and Stage 2)*:* Apply MDSAP duration of audit adjustments *(5.3)* as applicable. Use MDSAP P0008 algorithm contained within the chart above to calculate the total time necessary to accomplish all applicable audit tasks. From the calculated time necessary to accomplish all applicable audit tasks, add 25%. The result will reflect the duration of audit (i.e. time necessary to perform Stage 1 and Stage 2).

*Calculating Duration of Audit – for **non-initial** certification audits that **include** Stage 1*:* Apply MDSAP duration of audit adjustments *(5.3)* as applicable. Use MDSAP P0008 algorithm contained within the chart above to calculate the total time necessary to accomplish all applicable audit tasks. From the calculated time necessary to accomplish all applicable audit tasks, add additional time (if necessary) as deemed appropriate by the auditing organization to accomplish audit objectives. The result will reflect the duration of audit (i.e. time necessary to perform Stage 1 and Stage 2).

*The Auditing Organization shall determine how best to accomplish tasks of Stage 1 and Stage 2 with regards to off-site record review and on-site verifications. The Auditing Organization may combine elements of Stage 1 and Stage 2 to allow for a single on-site visit to the manufacturer. IMDRF N3 9.3.1

5.3 *Duration of Audit Adjustments:*

Duration of Audit can be adjusted when certain additional conditions are encountered.

5.3.1 Adjustments specific to Design and Development (when applicable)

5.3.1.1 If the organization to be audited does not engage in design and development activities, the audit of Design and Development can be limited to tasks 1 and 16.

5.3.1.2 If the organization to be audited manufactures medical devices that were

designed prior to regulatory design and development requirements and does not actively design new devices, the audit of Design and Development can be limited to tasks 1, 4 (Design Change Procedures) and 13 – 16.

5.3.1.3 For medical devices containing software, applicable design and development activities specific to the software may result in the duplication of design and development tasks.

Note: Some audit tasks may be accomplished concurrently during the accomplishment of a separate audit task. In this case, reference should be made in the audit report that multiple audit tasks were accomplished concurrently. The report should clearly reference where the findings of each audit task are discussed.

5.3.2 Adjustments specific to Production & Service Control (when applicable)

5.3.2.1 If the manufacturing process selected to be audited during a surveillance audit was comprehensively audited during a previous current MDSAP audit cycle audit and there have been no significant changes to the process or indicators of potential concerns, the time estimated for auditing this process may be reduced.

5.3.3 Adjustments specific to assessment of previously cited nonconformities

5.3.3.1 If the audit requires the assessment of corrections and/or corrective actions from previously cited nonconformities, each nonconformity should be considered a task under Measurement, Analysis and Improvement (MA&I) with the appropriate additional time allocated.

5.3.4 Adjustments specific to assessment of critical suppliers

5.3.4.1 Additional time should be added based on the number of critical suppliers, where necessary.

5.3.5 Adjustments based on Multiple Site Audits

5.3.5.1 When multiple site audits are conducted, the duration of audit for each individual site should be calculated. The total duration of audit is the cumulative duration of audit necessary to audit each individual site. Multiple site audits may require the duplication of audit tasks at multiple sites. Conversely, multiple sites may not have the same responsibilities and processes. Individual site duration of audit should be calculated based on the specific responsibilities and processes of that site. Sampling of design and manufacturing sites is not permitted.

5.3.6 Adjustments based on organization size

5.3.6.1 For organizations with fifteen (15) or fewer personnel, duration of audit may be reduced commensurate with the risk of the product or processes audited. The maximum allowable reduction of the duration of audit based on organization size shall be no more than 10% of the calculated duration of audit.

Note: All considerations affecting audit time calculations, including considerations not referenced within this document (e.g. as specified in ISO/IEC 17021-1:2015, clause 9.1.4) should be described in the recorded justification supporting the audit time determination.

6. Reference Documents

ISO/IEC 17021-1:2015 Conformity assessment – Requirements for bodies providing audit and certification of management systems Part 1:Requirements

ISO 9000:2015 Quality management systems – Fundamentals and vocabulary

MDSAP Audit Model

MDSAP Audit Model Companion Document

MDSAP AU F0008.1 Duration of Audit Calculation Spreadsheets and Instructions (To be used when calculating audits against ISO13485:2003 using MDSAP AU P0002.003)

MDSAP AU F0008.2 Duration of Audit Calculation Spreadsheets and Instructions (To be used when calculating audits against ISO 13485:2016 using MDSAP AU P0002.004)


MDSAP_AU_F0008.1.
002_Audit_Duration_C


MDSAP_AU_F0008.2.
001_Audit_Duration_C

7. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2013-12-13	Initial Release	Robert Ruff, FDA
002	2016-08-15	Document was revised to meet the new ISO/IEC 17021-1:2015 Requirements. Only minor changes were made.	Liliane Brown, FDA
003	2017-01-24	Following revisions were made: 1. reflect new terms contained in ISO/IEC 17021-1:2015 (e.g. duration of audit, audit time); 2. reflect revised specified requirements regarding the calculation of off-site audit time (preparation, report writing, etc.); 3. add "Duration of Audit Calculations" for audits including and excluding Stage 1 (S1); 4. reflect allowed adjustments are relative to duration of audit. QMS Manager: to request an expedited review and approval by the RAC. This is a deliverable promised during the December Ottawa forum. After RAC approval and posting to the web, please prepare and send a transmittal notifying AOs and RAs of the revised document's availability. The new procedure should be implemented when calculating times reflecting the use of MDSAP AU P0002.004 (revised audit model generated to reflect ISO/IEC 13485:2016). 5. created a new form (MDSAP AU P0008.2) to reflect the new Spreadsheet that was created to display the new audit time calculation algorithm based on the new audit model. 6. Title change from “Audit Time Calculation to Audit Time Determination”.	Robert Ruff, FDA

Version 003
Approval

Approved: Signature on file_____ Date: 2017-01-30
CHAIR, MDSAP RAC